

REMARKS

1. Indication of Allowable Subject Matter

Applicant greatly appreciates the Examiner's statement in the instant Office Action in which claims 15-18 have been indicated as allowable.

2. Response To Claim Rejections Under 35 U.S.C. § 102(b) in View of U.S. Patent No. 5,520,664

Claims 1, 4, 13, and 14 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bricault, Jr. et al. (U.S. Patent No. 5,520,664) because Bricault allegedly discloses polymeric implants having anti-microbial coatings of silver. The Office Action further alleges that silver and other anti-microbial metals inherently possess the property of altering an electrodynamic process of a portion of a the body, particularly the portion of the body containing wound exudates. The Office Action concludes that because Bricault discloses metals also disclosed in the present application, the conductive materials of Bricault must have the same resistance as the claimed subject matter. Lastly, the Office Action cites Figs. 5 and 6a which depict a tubular shaped catheter that allegedly is capable of draining a wound or body cavity. Applicant respectfully traverses these rejections on the grounds that Bricault does not disclose all of the elements of the claims.

A proper rejection of a claim under 35 U.S.C. § 102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983).

Claim 1 is amended to recite a medical device for treating a pathology of a living organism, comprising, at least one conductive layer, wherein the at least one conductive layer comprises a resistance less than about 1000 ohms/cm² and a biologically inert polymer which is at least partially coated with a metal or a metal alloy; and wherein the medical device is configured to alter the pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology. Support for this amendment is found in the specification as originally filed, for example on pages 30-32, and Applicant submits no new matter is introduced.

Bricault et al. does not anticipate claim 1 for at least two reasons. First, Bricault does not disclose a medical device that is configured to alter a pathology's electrical potential when the medical device is positioned to conductively bridge healthy surfaces surrounding the pathology. The present specification provides that the material and the configuration of the material in the medical device including the manner in which the conductor is coated on the biologically inert material, the geometry of the conductors, and the manner in which the layer is constructed all contribute to the ability of the medical device to affect electrical potentials (see page 32, lines 14-23).

Bricault discloses a catheter that is plated with an anti-microbial metal such as silver. The silver is deposited on the surface of the catheter in an "ultra-adherent" manner (col. 6, line 31) to produce a bactericidal/fungicidal surface treatment on a tissue contacting surface of the catheter (col. 1, lines 26-28). Thus, the device of Bricault uses silver and other metals to prevent microorganisms from growing on the surface of the catheter, and not for modulating the electrical potential of a pathology. Indeed, Bricault discloses devices that have a substantially non-leaching metal surface (col. 5, lines 58-63). Bricault does not disclose a medical device having at least one conductive layer, wherein the at least one conductive layer comprises a resistance less than about 1000 ohms/cm², and a biologically inert polymer which is at least partially coated with a metal or a metal alloy, and wherein the medical device alters the electrical potential of a pathology when positioned to conductively bridge healthy surfaces surrounding the pathology.

Second, nothing in Bricault references electrical potentials in any manner or medical devices that affect electrical potentials of a pathology by forming conductive bridges between surrounding healthy tissue. Moreover, Bricault does not disclose, expressly or inherently, altering a pathology's electrical potential by any means. The devices of Bricault are for the delivery of material, such as fluids, to a patient. Accordingly, Bricault does not anticipate claim 1, and Applicant submits that the rejection has been overcome.

Additionally, the Office Action provides no evidence to support the allegation that silver or anti-microbial metals inherently alter electrodynamic properties of a portion of a body with which they contact or that such an activity would be recognized by persons of ordinary skill in the art. Applicant respectfully requests the Examiner provide some objective evidence in support

of this inherent property of anti-microbial metals. In the absence of such objective evidence, Applicant respectfully submits the rejection is improper and should be withdrawn.

Moreover, Applicant points out that aspects of the presently claimed subject matter are directed to medical devices configured with anti-microbial metals in a manner to modulate electrical potentials, for example the electrical potential of a pathology. The claims have been amended to clarify that the resistance of the conductive layer not the conductive material is less than 1000 ohms/cm². Because the method of applying metals to surfaces and the configuration of the conductive layer affect the resistivity of the conductive layer and the medical device, the general application of a metal to a surface does not necessarily provide the conductive layer or medical device with a resistivity equivalent to the applied metal, for example a resistance lower than 1000 ohms/cm². Thus, Applicant respectfully submits that resistivity of the devices in the cited references cannot be determined simply because the devices include a metal, and therefore, the cited references cannot anticipate the claimed subject matter.

Claim 4 depends on claim 1, and therefore, incorporates the limitations of claim 1. As a result, claim 4 is not anticipated by Bricault for at least the reasons that claim 1 is not anticipated by Bricault.

Claim 19 is amended to recite the step of "altering the electrical potential of the pathology by conductively bridging healthy surfaces surrounding the pathology." Support for this amendment is found in the specification as originally filed, for example on pages 30-31. Thus, no new matter is introduced by this amendment.

Bricault does not disclose altering the electrical potential of a pathology with a medical device by forming a conductive bridge between healthy surfaces surrounding the pathology. Applicant submits that in light of the present amendment to claim 19, the rejection is overcome.

3. Response To Claim Rejections Under 35 U.S.C. § 102(e) in View of U.S. Patent No. 6,004,667

Claims 1, 4, and 19 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Sakurada et al. (U.S. Patent No. 6,004,667) because Sakurada allegedly discloses a wound dressing having a fibrous substrate coated with silver which inherently has a resistance of 1000 ohm/cm or less. The Office Action also suggests that Sukurada discloses that metallic ions may be distributed into the body without galvanic cell action, and that silver inherently alters

electrodynamic processes of a portion of a body with which it contacts. The Office Action also alleges that Sakurada discloses a conductive layer that inherently includes a biologically inert polymer because it is used on the human body where no galvanic cell action or energy source is required. Finally, the Office Action advises Applicant that steps (b) and (c) inherently occur when metallic ions from the substrate enter the body. Applicant respectfully traverses this rejection for the reasons below.

Sakurada discloses a bandage having a film of ultra-fine semiconductor and conductor particles melt injected onto a substrate. The conductor can be silver and the semiconductor can be TiO_2 . Sakurada does not disclose, among other things, a medical device having a conductive layer that alters the electrical potential of a pathology when positioned to conductively bridge healthy surfaces surrounding a pathology. Sakurada does not disclose or mention positioning a conductive layer of a medical device on a pathology to establish a conductive bridge between the tissue surrounding the pathology at all. Indeed, Fig. 10 of Sakurada discloses a bandage wherein the layer containing anti-microbial metal is surround by absorbent layers thereby preventing the metal containing layer from contacting tissue directly. Thus, not only does Sakurada fail to disclose all the elements of the claims, Sakurada fails to recognize one of the advantages of Applicant's invention - namely, promoting the healing of a pathology by passively altering the pathology's electrical potential. As noted above, the resistivity of Sakurada is not disclosed and cannot be determined on the basis that it includes a metal.

Independent claims 1 and 19 both generally recite a medical device or method for forming a conductive bridge between the surrounding surfaces of a pathology to alter the pathology's electrical potential. Sakurada fails to disclose at least this element of the claims, and therefore, Applicant respectfully submits that the rejection is overcome.

Claim 4 depends from claim 1, and is not anticipated by Sakurada for at least the same reasons claim 1 is not anticipated.

4. Response To Claim Rejections Under 35 U.S.C. § 102(b) in View of U.S. Patent No. 4,615,705

Claim 6 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Scales et al. (U.S. Patent No. 4,615,705) because Scales allegedly discloses anti-microbial implants

having a layer of conductive material. Applicant respectfully traverses this rejection because Scales does not disclose all of the elements of claim 6.

Claim 6 depends from claim 1 and further characterizes the medical device of claim 1 as an orthotic appliance. Because claim 6 depends from claim 1, claim 6 incorporates all of the limitations of claim 1. In particular, claim 6 requires that the medical device be configured to alter a pathology's electrical potential when the medical device is positioned to conductively bridge healthy surfaces surrounding the pathology. Scales does not disclose a medical device configured to alter the electrical potential of a pathology when the medical device conductively bridges the healthy tissues surrounding the pathology. Thus, for at least this reason, Scales does not disclose all the elements of claim 6 and cannot anticipate claim 6. Accordingly, Applicant submits the rejection is overcome.

Moreover, Scales describes implants not orthotics as claimed in Claim 6. Orthotics are known in the art as external devices, such as braces, used to facilitate or correct joint motion. See for example U.S. Patent Nos. 6,547,752, 5,891,068, and 5,842,294. Applicant submits that one skilled in the art would not consider orthotics to include implants. Accordingly, the implants disclosed in Scales are not orthotics, and therefore, Scales cannot anticipate claim 6.

5. Response To Claim Rejections Under 35 U.S.C. § 103

Claim 7 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Scales et al. Applicant respectfully traverses this rejection because Scales does not teach or suggest all of the elements of the claim. Claim 7 depends on claim 1 and therefore incorporates the elements of claim 1. The Office Action contends that one of ordinary skill in the art would have been motivated to use the anti-microbial coatings of Scales in any implant including a dental implant. Applicant respectfully disagrees.

It is well established that for a proper rejection of a claim under 35 U.S.C. § 103 as being obvious based upon a single reference, the reference must disclose, teach, or suggest, either implicitly or explicitly, all elements/features/steps of the claim at issue. See, e.g., *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981).

As discussed above, Scales does not disclose, teach, or suggest a medical device configured to alter a pathology's electrical potential either expressly or inherently. Because claim 7 depends from claim 1, claim 7 incorporates this element. Thus, Scales does not teach or suggest all of the elements of claim 7 and, therefore, Scales cannot render claim 7 obvious. Applicant submits the rejection is overcome.

Claims 3, 5, and 8-12 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakurada et al. Applicant respectfully traverses this rejection because Sakurada does not teach or suggest all the elements of the claims.

Claims 3, 5, and 8-12 ultimately depend on claim 1 and therefore incorporate the limitations of claim 1. As noted above, Sakurada does not disclose, teach, or suggest a medical device configured to modulate electrical potentials, for example, the electrical potentials of a pathology. Accordingly, Sakurada fails to teach or suggest all the elements of the claims and cannot render the claims obvious.

6. New Claims

Claims 23-33 have been newly added to further define and/or clarify the scope of the invention. Support for claims 23-29 is found in the specification as originally filed, for example, pages 30-31. Support for claims 30-33 is found, for example, on pages 38-39. Accordingly, no matter is introduced. New claims 23-33 are believed allowable over the prior art of record for at least the reasons claims 1-19 are allowable.

7. Claims 20-22

Applicant notes that claims 20-22 were cancelled without prejudice in the prior response filed on 01 April 2003.

8. Prior Art Made of Record

The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1, 3-19 and 23-33 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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